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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,402

06/30/2006

Yoram Groner

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8368

23405

7590

01/04/2007

HESLIN ROTHENBERG FARLEY & MESITI PC

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EXAMINER

SGAGIAS, MAGDALENE K

ART UNIT

PAPER NUMBER

1632

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,402	GRONER ET AL.	
	Examiner	Art Unit	
	Magdalene K. Sgagias	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Previous Office Action, Restriction requirement mailed 12/14/06 has been vacated in light of the one below.

Claims 1-48 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I claim(s) 1-13, drawn to a method of inhibiting inflammation in a subject in need thereof, comprising contacting cells of the subject with an active agent that induces up-regulation of RUNX3 expression in the cells, wherein the active agent comprises a polynucleotide encoding Runx3.

Group II claim(s) 1-13, drawn to a method of inhibiting inflammation in a subject in need thereof, comprising contacting cells of the subject with an active agent that induces up-regulation of RUNX3 expression in the cells, wherein the active agent comprises a polynucleotide encoding Runx3 promoter activator.

Group III claim(s) 14-20, drawn to a method for enhancing T cell-mediated immune response in a subject in need thereof, comprising contacting cells with an active agent that down-regulates the expression of RUNX3 in cells, thereby enhancing the T cell-mediated immune response.

Group IV, claim(s) 21-28, drawn to a method of testing the efficacy of a treatment for a chronic inflammatory disease comparing subjecting a mouse that is homozygous for a RUNX3 null allele to a putative treatment and determining the efficacy of said treatment by measuring the severity of symptoms characteristic of said disease exhibited by said mouse, in comparison to the severity of symptoms exhibited by the same mice not exposed to the treatment.

Group V, claim(s) 29-38, drawn to a method of predicting an increased risk for a chronic inflammatory disease in a subject comparing the steps of: (a) obtaining a test sample from the

Art Unit: 1632

subject to be assessed; and (b) determining the expression of RUNX3 in the sample, wherein when the expression of RUNX3 in said test sample is diminished compared to normal levels expressed in healthy subjects, said subject has an increased risk of susceptibility to a chronic inflammatory disease.

Group VI, claim(s) 39-43, drawn to method of testing the efficacy of a treatment for a chronic inflammatory disease comprising subjecting cells derived from a knock out mouse that is homozygous for a RUNX3 null allele to a putative treatment in vitro and determining the efficacy of said treatment.

Group VII, claim(s) 44-45, drawn to a kit for diagnosis of genetic susceptibility to a chronic inflammatory disease comprising at least one probe capable of determining at least one genotype associated with the RUNX3 gene, or the expression of the gene product encoded by this locus.

Group VIII, claim(s) 46-48, drawn to a pharmaceutical composition comprising a polynucleotide construct encoding RUNX3 or RUNX3 promoter activator.

The invention of Group I does not require a polynucleotide encoding Runx3 promoter activator of Group II. An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single inventive concept. Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. See 37 C.F.R 1.475 (a). If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and first recited invention of each of the other categories related thereto will be considered as the main invention in the claims. See 37 C.F.R 1.475 (d) and 37 C.F.R 1.476 (c). Accordingly, Groups I-VIII are not linked by a special technical feature.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

Art Unit: 1632


currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571) 272-3305. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, Jr., can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Magdalene K. Sgagias, Ph.D.
Art Unit 1632


DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800
